

510(k) SUMMARY

SUBMITTER:

Rockwell Medical, Technologies, Inc.
30142 Wixom Road
Wixom, MI 48393
Phone: 248-960-9009

DEC 23 2002

DATE PREPARED:July 22nd, 2002**DEVICE NAME:**

Dri-Sate Dry Acid Concentrate Mixes
for Bicarbonate Dialysate

CLASSIFICATION NAMES:

Concentrate Solutions for Hemodialysis
Accessories to Hemodialysis

PREDICATE DEVICE:

Rockwell Medical Dri-Sate Acid Concentrate Mixes
Fresenius USA, Inc. Granuflo Dialysate Concentrate

Device Description:

The Rockwell Medical Technologies, Inc. DRI-SATE Dry Acid Concentrates containing sodium diacetate, for bicarbonate dialysis contain salt, sugar, and non-sugar and powders formulated and intended for use in hemodialysis when mixed or proportioned with the appropriate volume of purified water and bicarbonate concentrate / powder. These powders when proportioned/ mixed in a three-stream dialysis machine with pre-treated or purified water meeting or exceeding AAMI Standards and a bicarbonate concentrate solution, may be used in conventional and commercially available hemodialysis machines or monitors as a hemodialysis solution. The hemodialysis powders presented in this 510K Notification are intended to be used in three stream hemodialysis machines in which an acidified concentrate is proportioned into one stream, a bicarbonate, chloride and sodium concentrate solution which has been prepared by mixing the powder with a specified volume of water, is proportioned into the second stream of the hemodialysis machine, and water is proportioned into the third stream. These three streams are then mixed to prepare a final proportioned hemodialysis solution. These types of a final hemodialysis solutions are commonly referred to as "Bicarbonate Hemodialysis Solutions." These proportioned hemodialysis solutions are then heated to body temperature and then perfused through the dialysis fluid compartment of artificial kidneys or hemodialyzers. These bicarbonate hemodialysis solutions are separated from the patient's blood by means of a semi-permeable cellulosic or non-cellulosic membrane which serves as a molecular weight selective barrier to the passage of molecules beyond a certain molecular weight. The molecular weight cut-off of each type of membrane may vary depending on the membrane type, manufacturing process, etc. The semi-permeable membrane in a hemodialyzer permits the passage of smaller molecular weight (less than 5,000 Daltons for conventional cellulosic membranes), ionized and non-ionized molecules, waste products and toxins (i.e. blood urea nitrogen, creatinine, potassium, etc.) contained in the patient's blood circulating through the dialyzer, to pass through the semi-permeable membrane into the bicarbonate hemodialysis solutions, exit the hemodialyzer, enter the hemodialysis monitor and exit the monitor and are ultimately discarded. The ionic and molecular composition of the hemodialysis solution establishes the concentration gradient between the blood and the hemodialysis solution passing through the hemodialyzer which permits the effective removal of waste products and toxins found in excess in the patient's blood during acute and end-stage renal failure.

Since different patients have different requirements for the removal rates and quantities of various molecules and toxins (i.e. blood urea nitrogen, creatinine, potassium, phosphate, magnesium, chloride, sodium calcium water, etc.) in acute and chronic renal failure, it necessitates having a variety of different bicarbonate containing hemodialysis solutions to satisfy the needs of all acute and end-stage renal failure patients. In addition, there a number of different types of hemodialysis machines which have different proportioning rates. The concentrate mixes and solutions presented in this 510K Notification are designed

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or formulated to be used with hemodialysis machines that proportion according to the following dilution ratios:

Stream 1	Stream 2 Acidified Concentrate Proportioning Ratios	Stream 3: Bicarbonate Concentrate Proportioning Ratios
Water	1:35.83 or 1:44.00 or 1:34.00	1:19.13 or 1:27.57 or 1:25.16

It is for these reasons that a manufacturer of these hemodialysis solutions and powders must provide a number of different formulations to contain varying concentrations of the various molecular weight components. The concentrations of these various molecular components are varied in the final hemodialysis solution within physiological and non-physiological ranges to permit the efficient removal of lack thereof from the patient's blood during hemodialysis. Please refer to the Labeling Section of this 510K for a complete listing of each formulation.

Predicate Devices:

The Rockwell Medical Technologies, Inc. . Dri-Sate hemodialysis concentrate powders are equivalent to the Rockwell Medical Dri-Sate Acid concentrate powders for bicarbonate hemodialysis as well as the Fresenius USA, Inc., Granuflo/Granulate Powder Dialysate Concentrates. Documentation concerning these hemodialysis bath concentrate powders is provided in Part B. of this Section.

Information contained within this section of this 510K Notification provides pertinent information on the proposed hemodialysis powders for bicarbonate hemodialysis and compares it to the same information for other commercially available hemodialysis bath concentrate powders. The Rockwell Medical Technologies, Inc. hemodialysis concentrate powders utilize the same chemicals and compositions as the predicate devices.

Examination of the enclosed information pertaining to the Rockwell Medical Technologies, Inc. . hemodialysis concentrate powders for bicarbonate hemodialysis demonstrates that this device is substantially equivalent in composition, intended use, packaging and labeling to other hemodialysis concentrate powders currently approved for commercial distribution in the United States by the FDA. There are no significant differences between these marketed products and our proposed device.

Device Name	Rockwell Medical Dri-Sate Acid Concentrate Mixes	Fresenius USA, Inc. Granuflo Concentrates
Intended Use	Acid Concentrate for Bicarbonate-containing hemodialysis solutions	Acid Concentrate for Bicarbonate-containing hemodialysis solutions
510K Document Number	K981003	K911459
Approval Date	June 16th, 1998	July 17th, 1991
FDA Regulatory Class	II	II

Intended Use:

The Rockwell Medical Technologies, Inc., Dri-Sate Dry Acid Concentrates for Bicarbonate Dialysate are indicated for use in acute and chronic hemodialysis and to be used with the appropriate hemodialysis machine/ monitor and bicarbonate concentrate.

This indication statement is essentially the same as the indication statement for the predicate device.

Technological Characteristics:

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Comparing the proposed device to the predicate device, both devices utilize the same range of chemical compositions, packaging and formulations. There are no significant differences.

Summary of Non-Clinical Tests:

In vitro testing was performed to determine the chemical composition and range of composition.. The results of these tests confirmed that the proposed device is equivalent to the proposed device for these parameters.

Clinical Test Results:

Clinical testing was not performed

Conclusions:

Testing performed on the Rockwell Medical Technologies, Inc. Dri-Sate Acid Concentrate Solutions and Powders for Bicarbonate Dialysate indicates that it is safe, effective, and performs as well as the predicate device, when used in accordance with the instructions for use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 2002

Mr. Gerald A. Fritz
Director of Quality/Operations
Rockwell Medical Technologies, Inc.
30142 Wixom Road
WIXOM MI 48393

Re: K022500
Trade/Device Name: DRI-SATE Dry Acid
Concentrates for Bicarbonate
Dialysate
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis system and
accessories
Regulatory Class: II
Product Code: 78 KPO
Dated: October 28, 2002
Received: October 31, 2002

Dear Mr. Fritz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

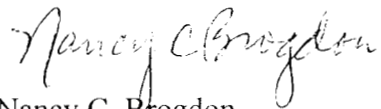
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K022500

DEVICE NAME: Rockwell Medical Technologies, Inc., Dri-Sate Dry acid
Concentrates for Bicarbonate Dialysate

INDICATIONS FOR USE:

Indications for Use Statement

The Rockwell Medical Technologies, Inc., Dri-Sate Dry Acid Concentrates for Bicarbonate Dialysate are indicated for use in acute and chronic hemodialysis and to be used with the appropriate hemodialysis machine/ monitor and bicarbonate concentrate.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use
(Optional Format 1-2-96)

David A. Heyman
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

(k) Number

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